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Proposed Rulemaking to Establish Criteria for the Importation of Designated Ruminants and Ruminant Products From Canada into the United States

Revised Environmental Assessment, March 2004

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I. What is this document and why is it being prepared?

Consistent with the National Environmental Policy Act of 1969 (NEPA) (42 United States Code 4321 *et seq*.) and its implementing regulations (40 Code of Federal Regulations (CFR) Parts 1500–1508), as well as the implementing procedures of the United States Department of Agriculture's (USDA) Animal and Plant Health Inspection Service (APHIS) (7 CFR Part 372), this environmental assessment (EA) explores potential environmental effects associated with a rulemaking proposal to allow some currently prohibited ruminants,[1] ruminant products, and ruminant by-products to be imported from other countries where there is a minimal risk that bovine spongiform encephalopathy (BSE, also known as "mad cow disease") could thereby become prevalent in the United States. Available evidence developed in risk analyses indicates that BSE is unlikely to become prevalent in the United States as a result of protection measures developed to prevent the spread and further introduction of the disease. However, this EA considers the potential environmental impacts from the proposed rulemaking.

II. What is the purpose of and need for the proposed action?

The purpose of the proposed action is to modify import regulations in order for the United States to allow the importation of ruminants, ruminant products, and ruminant by-products that do not substantially increase the risk of BSE entering the country. The need for the proposed action is to allow trade of certain live ruminants and ruminant products and by-products when there is no scientific basis for trade restrictions.

On May 20, 2003, the Canadian Food Inspection Agency (CFIA) reported a case of BSE in a beef cow in northern Alberta. The United States immediately added Canada to the list of regions where BSE is known to exist (9 CFR § 94.18(a)(1)). This action prohibited the importation of ruminants, ruminant products, and ruminant by-products that have been in Canada. After the U.S. import prohibition, Canada conducted an epidemiological investigation and implemented additional risk mitigation measures. Thereafter, Canada requested that the United States allow the

[1] Any of various hoofed, even-toed, usually horned mammals such as cows, sheep, goats, deer, giraffes, and camels. They characteristically have a stomach divided into four compartments and chew cud.

importation of certain low-risk live ruminants and ruminant products and by-products.

III. What alternatives are considered?

A. No action

The no action alternative would maintain the continued regulatory prohibition of the importation of ruminants, ruminant products, and ruminant by-products from Canada. The current regulations in 9 CFR Parts 93, 94, 95, and 96 prohibit the importation of live ruminants and most ruminant products and by-products from (1) regions where BSE exists (9 CFR § 94.18(a)(1)) and (2) regions that present an undue risk of introducing BSE into the United States via live ruminant or ruminant products or by-products because of inadequate surveillance or import requirements that are less restrictive than would be allowed for importation into the United States (9 CFR § 94.18(a)(2)).

B. Proposed action

The proposed rulemaking would allow for the importation of certain live ruminants and ruminant products and by-products, provided the requesting country seeking recognition as a minimal risk region demonstrates that it meets certain factors similar to the criteria recommended by the Office International des Epizooties (OIE).[2] This action would continue to protect against the further introduction and spread of BSE in the United States while removing unnecessary prohibitions on certain low-risk commodities from these regions. The factors that APHIS would have to address, through an evaluation, include whether the region has complied with the following:

(1) Maintains and, in the case of regions where BSE was detected, had in place prior to the detection of BSE, risk mitigation measures adequate to prevent widespread exposure and/or establishment of the disease. Such measures include the following:
   (a) Restrictions on the importation of animals sufficient to minimize the possibility of infected ruminants being imported into the region, and on the importation of animal products and animal feed containing ruminant protein sufficient to minimize the possibility of ruminants in the region being exposed to BSE;

[2] An organization that establishes international standards to facilitate trade for countries that are signatories to international trade agreements, while minimizing the risk of introducing diseases.

(b) Surveillance for BSE at levels that meet or exceed OIE recommendations for surveillance for BSE; and
(c) A ban on the feeding of ruminant protein to ruminants that appears to be an effective barrier to the dissemination of the BSE infectious agent, with no evidence of significant noncompliance with the ban.

(2) In regions where BSE is detected, an epidemiological investigation is conducted sufficient to confirm the adequacy of measures to prevent the further introduction or spread of BSE, and such measures are continued; and
(3) In regions where BSE is detected, additional risk mitigation measures are taken as necessary, following the BSE outbreak, and such measures are continued.

CFIA has requested the United States to recognize Canada as a minimal risk BSE region, thus allowing imports of certain live ruminants and ruminant products and by-products into the United States. For the list of low-risk products and specific risk-reduction strategies associated with CFIA's request, refer to the risk assessment, "Risk Analysis: BSE Risk from Importation of Designated Ruminants and Ruminant Products from Canada into the United States,"(hereby incorporated by reference) prepared by APHIS in October 2003.

IV. What is BSE?

BSE, commonly referred to as "mad cow disease" is a slowly progressive, degenerative disease that affects the central nervous system (CNS) of adult cattle. BSE belongs to a family of diseases known as transmissible spongiform encephalopathies (TSE). TSEs share some common characteristics, including a prolonged incubation period ranging from a few months to years and progressively debilitating neurological illnesses, which are always fatal. The typical incubation period for BSE is 2 to 8 years. Following the onset of clinical signs, the animal's condition deteriorates until it either dies or is destroyed. This process usually takes from 2 weeks to 6 months.

The causative agent of BSE has not been fully characterized, but three possibilities have been proposed: an unconventional virus, a prion (a self-replicating protein), or a virino (an incomplete virus). Currently, the most accepted theory is that the agent is a prion protein. The BSE agent is extremely resistant to heat, ultraviolet light, ionizing radiation, and common disinfectant processes, and it also does not evoke any detectable immune response or inflammatory reaction in host animals. Transmission

of BSE is believed to be spread to cattle through consumption of contaminated meat and bone meal from cattle with previously unidentified BSE. Tissues of particular risk include, but are not limited to, the brain, spinal cord, and eyes. BSE does not appear to be transmitted via contact between cattle or between cattle and other TSE-affected species. Some evidence suggests that maternal transmission may occur at an extremely low level (Wilesmith *et al.*, 1997).

V. What are the risks that the prevalence of BSE could be increased in this country?

A. Under the current regulatory system

To prevent BSE from entering the United States, since 1989, APHIS has restricted importation of live ruminants and ruminant products and by-products (e.g., fetal bovine serum, meat-and-bone meal, bonemeal, bloodmeal, offal, fats, and glands) from countries where BSE has been diagnosed. The Food and Drug Administration (FDA), in 1997, established regulations that prohibit the feeding of most mammalian proteins to ruminants in the United States because the primary source of transmission of BSE has been shown to be proteins derived from BSE-infected cattle in feed. Because of concerns about cross-contamination of rendered products of nonruminant origin with the BSE agent, APHIS, since 2000, has prohibited all imports of rendered animal protein products, regardless of species, from BSE-infected countries.

A risk assessment (Cohen *et al.*, 2001), "Evaluation of the Potential for Bovine Spongiform Encephalopathy in the United States," by the Harvard Center for Risk Analysis and Tuskegee University (hereafter referred to as the Harvard risk assessment), found that, owing to the already ongoing Federal programs, the United States is highly resistant to the spread of BSE in cattle herds and humans. The Harvard risk assessment regarded the feed ban as the United States' most effective means of BSE prevention.

Although safeguards were in place to prevent BSE infection, on December 23, 2003, USDA, APHIS announced a preliminary diagnosis of BSE in a single dairy cow in Washington State. On December 25, 2003, the United Kingdom Veterinary Laboratories Agency, which serves as an international reference laboratory for diagnosis of BSE, confirmed the diagnosis.

APHIS, in collaboration with CFIA, traced the birth of the BSE-positive cow to a dairy farm in Alberta, Canada. The cow was moved to the United States in September 2001 along with 80 other cattle from the Alberta, Canada, dairy farm. A total of 255 "Animals of Interest" (animals that were or could have been from the source herd in Alberta, Canada) were identified on 10 premises in Washington, Oregon, and Idaho. All 255 animals were depopulated and examined for the presence of BSE, and all were negative.

B. Under the proposed action

The proposed rulemaking includes factors that address the same issues addressed by the criteria of OIE for minimal risk classification.

Canada maintains it generally meets the OIE criteria for a minimal risk country. Specifically, the OIE code (OIE, 2002) provides for countries with indigenous cases of BSE to be categorized as minimal, moderate, or high risk based on established criteria. The primary differentiating standard for these designations is the incidence rate of indigenous cases. For a minimal risk country, the incidence rate must have been less than one case per million during each of the last four consecutive 12-month periods within the cattle population more than 24 months of age. The incidence rate for Canada has been 0 for 3 years and two animals in 5.5 million over the last 12-month period. This is within the parameters for a minimal risk country, and well below the parameters for a moderate risk country.

OIE criteria currently require that a country has had an effective feed ban in place for 8 years. The feed ban in Canada has been in place for 6 years. However, Canada has submitted evidence to show a history of stringent import control measures since 1990, a strong surveillance system since 1992, and appropriate additional mitigation actions taken as necessary. Canada recently added an additional measure, in response to the BSE find, to enhance food safety controls regarding BSE. The new measure requires that specified risk materials (SRMs) be removed from cattle at time of slaughter. SRMs are tissues that, in BSE-infected cattle, contain the agent that may transmit the disease. In addition, Canada has had a regulatory system for beef slaughter and processing that has been deemed equivalent to the U.S. system.

APHIS conducted a risk analysis that was published before the finding of an additional cow of Canadian origin in the State of Washington. In its Explanatory Note explaining why the detection of the BSE-infected cow in the United States does not affect the conclusion of the risk analysis,

APHIS explains the following:

- Both of the BSE cases of Canadian origin occurred in cattle born before the Canadian feed ban was implemented, both cows were older than 30 months of age when they were diagnosed as infected, and infection presumably occurred prior to or around the time the Canadian feed ban was enacted in August 1997.

- The finding of an imported case in a cow more than 30 months of age has little relevance to an analysis of risk under the proposed mitigation measures, beyond the implications for BSE prevalence in Canada.

- The proposed rule was not in effect in 2001 when the cow in question, which was more than 4 years old at the time, entered the United States. Under the proposed conditions, the animal would not have been allowed entry into the United States.

The APHIS risk analysis describes the risk-reduction strategies that would provide multiple safeguards against BSE and determined that with the surveillance, prevention, and control measures implemented by Canada, and the existing and proposed mitigation measures for specific animals and animal products intended for import, the risk of BSE-infected cattle being imported into the United States from Canada would be low. APHIS considered the factors discussed in the original analysis and the existing and proposed risk mitigation measures and determined that an additional BSE case of Canadian origin does not significantly alter the original risk estimate.

VI. What are the nature and extent of environmental effects that could be expected from BSE from the implementation of the proposed rulemaking in this country?

According to the NEPA implementing regulations, criteria set forth in 40 CFR § 1508.27(b) should be considered in this environmental assessment. Not all criteria are applicable; those that are applicable will be considered below, principally for the proposed action. The degree to which the no action alternative potentially could adversely affect all aspects of environmental quality being considered, while not zero, is less than that associated with the proposed action. Further discussion will

focus only on potential environmental effects associated with the rulemaking proposal.

A. The degree to which the proposed action affects public health or safety (40 CFR § 1508.27(b)(2))

There appears to be a causal link between variant Creutzfeldt-Jakob (vCJD), a TSE that affects humans, and the consumption of beef products contaminated with the BSE agent. A small number of vCJD cases has been reported, primarily in the United Kingdom, occurring in people who consumed beef that may have been contaminated. As of December 2003, a total of approximately 153 cases of vCJD have been reported worldwide. The one reported case of vCJD in the United States was of a woman who contracted the disease while residing in the United Kingdom. The symptoms appeared years later after the woman moved to the United States.

1. Actions to protect public health and safety from BSE

APHIS and the Food Safety Inspection Service (FSIS) developed a step-by-step action plan in the event a case of BSE were to be detected in the United States. The plan outlines those events that should take place, including identification of a suspect animal, confirmation, the epidemiologic investigation, animal and herd disposition activities, and communication of information. The plan has been shared with other government agencies that have developed their own plans to coordinate with those of APHIS. A summary of the BSE response plan is available on the Internet at the following web site: http://www.aphis.usda.gov/lpa/issues/bse/bsesum.pdf. The BSE Emergency Disease Guidelines detail acceptable disposal methods that should be used to dispose of BSE-suspect carcasses.

BSE-infected carcasses or tissue must be disposed of in such a way as to destroy the pathogen and eliminate, to the greatest extent possible, the spread of disease and risk of transmission to other animals, wildlife, and humans. The disposal method chosen should also be the most environmentally acceptable in regard to the local geography, topography, type of animal and disease, numbers of carcasses to be disposed, and disposal options available. The Resource Conservation and Recovery Act (RCRA) of 1976 provided the Environmental Protection Agency (EPA) the authority to develop and establish regulatory programs to manage solid waste, hazardous waste, medical waste, and underground storage tanks.

There are four primary disposal methods for diseased animal carcasses. Before a method of disposal is selected, there are many factors that must be considered. Field personnel should inquire with environmental

authorities concerning Federal, State, and local regulations that may impose restrictions on the selected disposal method (USDA, APHIS and FSIS, 1998). APHIS must comply with all applicable local, Federal, and State environmental regulations to minimize any environmental effects from these methods of disposal. Disposal methods include (1) air curtain incineration, (2) alkaline hydrolytic tissue digestion, (3) sanitary landfill disposal, and (4) burial.

a. Air Curtain Incineration

Air curtain incineration of carcasses and other infected materials is expected to destroy most prions and other toxic substances. Incineration, although more expensive than burial, is the preferred disposal method for BSE-suspect carcasses (USDA, APHIS and FSIS, 1998). The incinerators are designed to attain operating temperatures of 1800 ˚C to 2800 ˚C. These high temperatures at the stack flue eliminate nearly all smoke and particulates. These emissions pose little if any air contamination concerns. The remaining ash is expected to generally be free of toxic substances, but there may be some viable prions present in the ash due to variability of incineration temperature within the unit and incomplete combustion of all materials burned. Proper collection and disposal of this ash in a sanitary landfill should eliminate any residual toxins or prions of concern. These incinerators generally are not placed near residential or other locations that the general public would frequent. The majority of the BSE prions occur in the CNS of BSE-infected animals. With the inability to ensure consistent burning of the ashes within the incinerator, disposal of the affected head tissues may be achieved via alkaline digestion (slower but more complete elimination of prions) and the body tissues (most of the animal) may be sent to the incinerator where more material can be efficiently handled and there are still low risks of some prion survival due to inadequate combustion temperatures.

b. Alkaline Hydrolytic Tissue Digestion

Alkaline hydrolytic tissue digestion is an effective technique to eliminate BSE prions in infected tissues, but the digesters cannot handle as much material as air curtain incinerators. The largest available alkaline digesters can adequately handle 14,000 pounds per day (2 loads at 7,000 pounds per load).

As mentioned previously, this disposal technique could be combined with incineration to ensure maximum efficiency of treatment and maximum elimination of prion risks. These units are placed in secure locations where access is restricted and residential and public lands would not be near these facilities. Any remaining effluent from the digester could be

hydrated (water-evaporated) and the solids disposed of in secured sanitary landfills. Any odors or other emissions would pose no environmental risks.

c. Sanitary Landfill Disposal

The primary concerns about sanitary landfills relate to their ability to contain any remaining infective prions or other potentially hazardous substances associated with the carcasses and to prevent any runoff to surface water or any leaching to groundwater. The linings of sanitary landfills are such that movement of prions or other substances is largely precluded. These facilities are required to adhere to water quality standards set by EPA and State agencies. Contamination of soil or water outside the landfill liner is not anticipated. The landfill site access is restricted. The enclosures surrounding the landfill should keep out most people and wildlife. Review and monitoring of individual landfill sites is required by Federal and State laws to ensure that criteria for containment of hazardous substances are met. As with other samples and carcasses, handling and transport to the disposal pits will require care to prevent any cross-contamination of vehicles or other potential fomites.

d. Burial

Burial is allowed only if no other avenues for carcass disposal are available. The burial site may be on the affected farm, at the diagnostic laboratory where the carcass is examined, or in a local landfill. The site should be inaccessible to animals, removed from populated areas, not used for agricultural purposes, clearly marked, and properly protected. Burial sites should also be located a sufficient distance from underground utility lines, septic systems, water wells, and surface water.

Burial trenches are at least 9 feet deep with floor dimensions of 7×2 feet per adult bovine carcass. The carcasses should be covered with at least 6 feet of soil to avoid attracting wildlife that could possibly spread the disease. The soil should not be too tightly packed to avoid leakage of gas formations from the cracked soil (USDA, APHIS and FSIS, 1998).

In conclusion, prions are very difficult to inactivate and require rigorous treatment. The higher the solids content of the waste, the more rigorous the treatment required. Evaluations conducted by EPA have reported prions ability to survive boiling and autoclaving. Chemical treatment and gamma irradiation can be used to inactivate prions. The required irradiation dose is related to pathogen size. As the size decreases, the gamma dose increases, because it is harder for the gamma irradiation to hit the specific sensitive targets in the smaller infectious agents

(EPA, 2002). EPA also addresses the speculation in regards to the link between mineral deficiency, enhanced oral manganese (Mn) uptake, and Mn-catalyzed denaturation of copper-free prion protein to the pathogenic prion protein, which might explain the enhanced occurrence of some prion diseases in certain world regions (EPA, 2004a).

Currently, there is a limit in the amount of definitive information available specific to prions and TSEs. However, research on prions and TSEs is ongoing. The National Academy of Sciences has published a report, "2004 Advancing Prion Science: Guidance for the National Prion Research Program" (NPRP). In this report, the Institute of Medicine's (IOM) Committee on TSEs: Assessment of Relevant Science recommends research to close significant gaps in present knowledge of TSEs and techniques to strengthen the United States research infrastructure for studying these diseases. The committee determined that the scientific community must first answer fundamental questions about TSEs and prions, to develop the tools necessary to protect human and animal health. Therefore, the committee recommends that NPRP fund basic biomedical research on the structural features of prions; the molecular mechanisms of prion replication; the mechanisms of TSE pathogenesis; and the physiological function of prion protein, the normal form of the misfolded protein of prions. The committee also recommends that NPRP support research on the epidemiology and natural history of TSEs. This report fulfills a request of the U.S. Army's Medical Research and Materiel Command for advice from the IOM on the most effective research agenda for the NPRP, established by the U.S. Congress in 2002 (National Academy of Sciences, 2004).

2. Preventive actions to protect public health and safety

The Harvard risk assessment identified three pathways or practices that could contribute most either to increased human exposure to the BSE agent or to the spread of BSE if it should be introduced into the United States. The pathways or practices are (1) noncompliance with the feed ban, (2) rendering of downer cattle (cattle that cannot rise from a recumbent position or that cannot walk) including cattle that die on the farm, and (3) inclusion of high risk tissue, such as brain and spinal cord, in edible products.

Because the primary source of transmission of BSE has been shown to be proteins derived from BSE-infected cattle in feed, the Food and Drug Administration (FDA) has established regulations that prohibit the feeding of most mammalian proteins to ruminants in the United States. To prevent BSE from entering the United States, since 1989, APHIS has restricted importation of live ruminants and ruminant products (e.g., fetal bovine serum, meat-and-bone meal, bonemeal, bloodmeal, offal, fats, glands) from countries where BSE has been diagnosed. Also, because of

concerns about cross-contamination of rendered products of nonruminant origin with the BSE agent, since 2000, APHIS also has prohibited all imports of rendered animal protein products, regardless of species, from BSE-infected countries.

Cattle sent for slaughter in the United States are evaluated by the FSIS for signs of neurologic disease. Cattle exhibiting neurological signs on antemortem inspection are condemned and are not used for human food. Central nervous system tissue from these animals is forwarded to APHIS laboratories for pathologic examination.

On January 12, 2004, FSIS issued a interim final rule requiring that establishments that slaughter cattle and establishments that process the carcasses or parts of cattle develop, implement, and maintain written procedures for the removal, segregation, and disposition of SRMs (section 310.22(d)(1)). The agency did not prescribe specific procedures that establishments must follow in the interim final rule, believing that establishments should have the flexibility to implement the most appropriate procedures that will best achieve the requirements of this rule. Establishments are responsible for ensuring that SRMs are completely removed from the carcass, segregated from edible products, and disposed in an appropriate manner. Establishments must address their control procedures in their HACCP (Hazard Analysis and Critical Control Point) plans, Sanitation SOPs (Standard Operating Procedures), or other prerequisite programs. FSIS will ensure the adequacy and effectiveness of the establishment's procedures. Section 310.22(d)(4)) also requires that establishments that slaughter cattle and establishments that process the carcasses or parts of cattle maintain daily records that document the implementation and monitoring of their procedures for the removal, segregation, and disposition of SRMs, and that the establishments make these records available to FSIS personnel on request. FSIS will assess whether additional guidance is necessary.

FSIS amended the regulations that prescribe requirements for dead, dying, disabled, or diseased and similar livestock in 9 CFR § 309.3 to require that non-ambulatory disabled cattle be condemned and disposed of in accordance with 9 CFR § 309.13. Unless another provision in 9 CFR part 309 applies, under § 309.13, condemned livestock must be killed by the establishment, if not already dead. Such animals cannot be taken into the establishment to be slaughtered or dressed or conveyed into any department of the establishment that is used for edible products. The carcasses of condemned livestock must be disposed of in the manner provided for in 9 CFR part 314. Under 9 CFR part 314, condemned carcasses must be disposed of by “tanking,” i.e., inedible rendering (9 CFR § 314.1). For those establishments that do not have facilities for

"tanking," condemned carcasses may be disposed of by incineration or denatured by crude carbolic acid, cresylic disinfectant, or any other proprietary material approved by the Administrator of FSIS (9 CFR § 314.3). In addition, the Administrator recognizes the use of activated charcoal to denature inedible materials.

USDA and FDA have adopted the following safeguards to further reduce the potential risk of future exposures to the BSE agent:

1. USDA issued interim final rules on January 12, 2004, requiring immediate implementation of the following safeguards:

- Prohibit any material from "non-ambulatory disabled livestock" (downer cattle) for human food, although the disposition of non-ambulatory disabled livestock not taken to slaughter has yet to be determined.

- Prohibit the use in human food of certain SRMs that are known to harbor the highest concentrations of the infectious BSE agent. The following tissues are designated as SRMs: skull, brain, trigeminal ganglia, eyes, vertebral column, spinal cord, and dorsal root ganglia of cattle over 30 months of age and the small intestine of cattle of all ages.

- Prohibit the use for human food of products known as mechanically separated beef, a product that may contain SRMs.

- Require additional process controls for meat derived by the process known as advanced meat recovery (AMR) and prohibits the use of AMR processes on vertebral column or skulls of cattle greater than 30 months of age. Meat obtained by AMR may be used for human food, but sampling procedures must be in place to ensure that neither spinal cord nor dorsal root ganglia are present in the final product.

- Prohibit slaughter of bovines by the use of air-injected stunning (pneumatic stun guns).

(Additional information on recent USDA rulemaking and notices can be accessed at www.fsis.usda.gov/oa/news/2004/bseregs.htm.)

2. FDA announced the imminent issuance of an interim final rule to institute the following changes:

- Prohibit the use of ruminant blood and blood products in feed for ruminants.

- Prohibit the use of "poultry litter" as a feed ingredient for ruminants.

- Prohibit the use of "plate waste" (uneaten meat and meat scraps collected from restaurant operations) as a feed ingredient for ruminants.

- Minimize the opportunities for cross-contamination of feeds intended for ruminants with feeds for non-ruminant animals by requiring that equipment, facilities, and production lines be dedicated to the production of non-ruminant animal feeds if they use proteins prohibited in feeds for ruminants.

(Additional information on recent FDA rulemaking and notices can be accessed at http://www.fda.gov/oc/opacom/hottopics/bse.html).

USDA is in the process of working to implement a national identification system to track animals of various species through the livestock marketing chain to enhance the speed and accuracy of the response to animal diseases such as BSE.

3. Preventative measures for handling infected or potentially infected animal remains

EPA classifies animal waste as a type of biomedical waste (EPA, 2004b). Animal waste is defined as waste animal carcasses, body parts, and bedding of animals that are known to be infected with, or that have been inoculated with, human pathogenic microorganisms infectious to humans. Biosafety level 4 disease waste is waste contaminated with blood, excretions, exudates, or secretions from humans or animals who are isolated to protect others from highly communicable infectious diseases that are identified as pathogenic organisms (Washington State Legislature, 2004). Thus, BSE-infected animals and animal remains should be handled as hazardous waste.

In summary, given (1) the relatively low initial risks, including the attenuated nature of the pathways through which the disease would be communicated, (2) the risk-reduction strategies developed in the APHIS risk assessment, (3) the APHIS action plan to deal with BSE when discovered in the United States, (4) the heightened vigilance on both sides of the border stemming from a single BSE find in both the U.S. and Canada, (5) approval and implementation of the proposal, particularly as applied to Canada, and (6) additional safeguards implemented by USDA to protect the food supply of ruminants and humans, implementation of the proposed rule could not be viewed as increasing significantly the risk of potentially adverse public health effects.

B. The degree to which the possible effects on the human environment are highly uncertain or involve unique or unknown risks (40 CFR § 1508.27(b)(5))

The exact quantitative relationship between human exposure to BSE agents and the likelihood of human disease is unknown; the likelihood that humans will develop vCJD under various scenarios is entirely speculative and cannot be assessed. Similarly, potential human exposure to the BSE agent through products containing ingredients of bovine origin, such as some pharmaceuticals, gelatin, beef stocks, extracts, and flavorings are not addressed in the Harvard risk assessment. If BSE should enter the United States, the Harvard risk assessment indicates that, at most, probably only a small amount of potentially dangerous tissues would reach the human food supply.

Although the Harvard risk assessment concludes that it is unlikely that U.S. cattle would become infected from eating BSE-contaminated feed because of the FDA ban on feeding ruminant protein to ruminants, there is some uncertainty with regard to the rate of misfeeding prohibited feed (containing ruminant protein) to cattle on farms that raise both cattle and either pigs or chickens and, (2) the proportion of feed produced that is accidentally mislabeled as ruminant protein-free at the feed-producing facility.

C. The degree to which the action may establish a precedent for future actions with significant effects or represents a decision in principle about a future consideration (40 CFR § 1508.27(b)(6)) and whether the action is related to other actions with individually insignificant but cumulatively significant impacts (40 CFR § 1508.27(b)(7))

Implementation of the proposed rule, particularly as applied to Canada, will set a precedent for future actions by establishing criteria through which other BSE-infected countries may submit requests to import certain live ruminants and ruminant products and byproducts that meet the criteria for being unlikely to contain the BSE infectious agent. At this time, it is speculative as to which BSE-infected countries or how many countries would request recognition and meet the minimal-risk criteria. While the potential cumulative effects of this proposed action cannot be predicted, each petition that APHIS receives from a country would require an assessment of the environmental effects of the petitioned action in combination with the actions of all countries whose requests previously

have been approved. Monitoring the potential environmental impacts in this manner is both would allow APHIS to revisit the issue of cumulative effects with each request.

If BSE finds were to occur at an increased rate in the United States resulting from implementation of this proposed rulemaking, the potential for cumulative effects relative to disposal of prion-infected carcasses would need to be considered. The potential for cumulative impact to soil and groundwater would need to be considered for sanitary landfills that could be handling disposal of animal carcasses infected by another TSE disease, such as chronic wasting disease. If air curtain incineration is used for both BSE-infected and other TSE-infected carcasses, the potential for cumulative impact from emissions would need to be considered. The significance of the impact would depend upon the increased rate of BSE finds, the rate of other prion disease finds, disposal methods of infected animals in the location, and the persistence, fate, and transport of prions in the environment, all of which are still being explored.

D. The degree to which the action may adversely affect an endangered or threatened species or its habitat (40 CFR §1508.27(b)(9))

Endangered Species Act. Section 7 of the Endangered Species Act (ESA) and ESA's implementing regulations require Federal agencies to insure that their actions are not likely to jeopardize the continued existence of endangered or threatened species or result in the destruction or adverse modification of critical habitat.

TSEs have been reported in Europe in captive wild ruminants, cats, and monkeys and are believed to have resulted from BSE-contaminated feed. Six endangered ruminant species were considered as potentially affected by this proposed rule as a result of the possibility of contact by these wild species with BSE-infected cattle or ingestion of contaminated feed (see table 1).

Table 1. Endangered wild ruminant species in the United States at risk from transmissible spongiform encephalopathies.

Common Name	Scientific Name	Listing Status
Woodland caribou	*Rangifer tarandus caribou*	Endangered
Columbian white-tailed deer	*Odocoileus virginianus leuceurus*	
Key deer	*Odocoileus virginianus clavium*	
Sonoran pronghorn	*Antilocapra americana sonoriensis*	
Bighorn sheep	*Ovis canadensis*	
Sierra Nevada bighorn sheep	*Ovis canadensis californiana*	

No evidence is available to show that BSE is spread by contact between unrelated cattle or from cattle to other species. In addition, animal feed imported from Canada that might be fed to wild ruminants in the United States should not contain BSE-contaminated animal products. The FDA has established regulations that prohibit the feeding of most mammalian proteins to ruminants in the United States. Thus, no effect is anticipated on listed wild ruminant species potentially susceptible to TSEs.

One threatened and three endangered wild cats were considered for risk of infection from BSE because of the possibility that they could feed on BSE-infected cattle or carcasses of cattle (see table 2).

Table 2. Listed wild cats known to feed on domestic cattle or cattle carcasses.

Common Name	Scientific Name	Listing Status
Jaguar	*Panthera onca*	Endangered
Canada lynx	*Lynx canadensis*	Threatened
Florida panther	*Puma (=Felis) concolor coryi*	Endangered
Eastern puma (=cougar)	*Puma (=Felis) concolor couguar*	

Based upon the effectiveness of the criteria included in the proposed rule to reduce BSE risk, implementation of the proposed rule is not expected to have any effect on federally-listed wild cats or their habitats.

VII. What are the conclusions?

The risk of introducing BSE into the United States as a result of the proposed rulemaking appears to be low based on past and more recent risk mitigation measures and safeguards implemented in Canada and the United States. Therefore, allowing certain live ruminants and ruminant products and by-products to be imported from minimal risk BSE regions should not significantly affect the quality of the human environment.

VIII. What agencies and persons have been consulted?

Regionalization Evaluation Services
National Center for Import and Export
Veterinary Services, APHIS, USDA

Emergency Programs
Veterinary Services, APHIS, USDA

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